K011327

AUG 15 2002

ZMS Zander Medical Supplies

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510(k) Summary

20 April 2001

Submitted by: Zander Medical Supplies, Inc.
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(561) 569-5955
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Contact: Friedel MW Zander, President/CEO
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Manufactured by: Biotronics
Unit 1, Morton Farm
Morton Eye, Leominster
HR6 ODP U.K.
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Contact: Steve Goode, Managing Director
E-mail: sales@biotronics.net

Prepared by: Friedel MW Zander
Zander Medical Supplies, Inc.

Trade Name: Biotronics DB1 Embryo Freeze
Common Name: DB1

Class: II **CFR:** 884.6120 **Procode:** 85 MQG

Predicate Device: There is currently no Predicate Device for a freezer of this sort.

Device Description:

The DB1 EmbryoFreeze has been developed to meet the requirements of specialists working in both human and veterinary embryo transfer. This portable freezer can be used in most locations with its own internal battery and is easy to program and use, with a throughput of up to 100 straws per cycle. The DB1 is a "solid state" design without moving components. There are no solenoid valves, pumps or motors. The straw plate is precisely controlled and the temperature is balanced against the cold liquid nitrogen (LN2) chamber.

Intended Use:

The DB1 EmbryoFreeze is used for freezing biological materials such as embryos, oocytes, etc., in cryostraws for cryopreservation using Liquid Nitrogen (LN_2).

Technical Details:

Power Supply

Internal Battery(s):	12V-DC 7Ah. Sealed Lead Acid. 1 or 2 installed.
External DC supply:	12V-DC 10A fuse. Maximum 14V-DC.
Mains Power:	85V-AC to 264V-AC 47 to 440 Hz or 120V-DC to 370V-DC 2.5A.
Run time on internal battery:	Approximately 3 hours on one battery / 6 hours on two batteries.

Fuses

Mains:	5A (5A spare)
Heater:	5A
12V-DC Input:	10A (internal)
Internal Battery:	10A (internal)
Internal Power Supply:	4A (internal)

LN_2 Supply

LN_2 Capacity:	Approximately 2.5 litres.
Static Holding Time:	Up to 2 hours.
LN_2 Consumption:	3 hour use from 2.5 litres (after initial boil off).

Case

Size:	L=405mm x W=270mm x H=295mm (including feet).
Weight:	9.5 Kgs with one battery, additional battery add 2.65 Kgs.
Material:	Polyurethane high density foam.

Controls

Display:	240 x 120 pixels, 30 x 16 characters.
Back Light:	Fluroescent EL tube.
Buttons:	Push button with green LED.
Alpha Wheel:	Optical rotary encoder.
On/Off Button:	Push on and push off.

Connections

Mains:	Filtered and fused (plus spare fuse).
12V-DC:	Internally fused, centre positive.
Printer:	Standard 25 way parallel printer interface (HP PCL Compatible).
Serial:	Standard 9 pin RS232 interface. Use null modem lead.
Service:	12 way of which 3 are COM, N/O & N/C alarm relay outputs.

General Details:

Cooling & Heating Rates:	Minimum rate: 0.1°C Maximum rate: 5.0°C
Temperature Range:	Minimum temperature: –80°C Maximum temperature: 150°C
Timed Hold Range:	Minimum timed hold: 1 minute Maximum timed hold: 99 minutes Setting resolution: 1-minute steps. Timing resolution: 0.01 seconds.
Control Resolution:	0.01°C. Data logging and display 0.1°C
Aim Temperature Resolution:	1°C
Maximum Program Lines:	8
Number of Stored Programs:	8
Password Characters:	4
Data Log Frequency:	Log recorded every 10 seconds when running a program.

Label Examples:

Importer & Distributor:

Manufacturer:

A sample of the Manufacturer's labeling can be found in the User Manual, page 4. It is screen-printed onto the case, with the exception of the CE Label, the serial number on the back and mains warning label on the base. These are self-adhesive standard labels.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 15 2002

Mr. Friedel M. Zander
President /CEO
Zander Medical Supplies, Inc.
755 8th Court, Suite 4
P.O. Box 650790
VERO BEACH FL 32965-0790

Re: K011327
Trade/Device Name: DB1 Embryo Freeze
Regulation Number: 21 CFR 884.6120
Regulation Name: Assisted reproduction accessories
Regulatory Class: II
Product Code: 85 MQG
Dated: July 30, 2002
Received: Aug 1, 2002

Dear Mr. Zander:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

ZMS
Zander Medical Supplies

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510(k) NUMBER (IF KNOWN) : K011327

DEVICE NAME : DB1 EmbryoFreeze

INDICATIONS FOR USE :

The DB1 EmbryoFreeze is used for freezing biological materials such as embryos, oocytes, etc., in cryostraws for cryopreservation using Liquid Nitrogen (LN2).

David G. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K011327

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED).

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter-Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)